

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

The specification has been amended as several places to correct inadvertent typographical errors. In particular, reference numeral "3a" referring to the main section side outer tube has been changed to -3b—for purposes of consistency with the description in the remainder of the specification.

New dependent Claim 10 has been added and is readable on the elected invention. Claims 4-9 remain withdrawn from further consideration as being directed to the non-elected invention. Thus, the only claims currently at issue are Claims 1-3 and 10, with Claim 1 being the only independent Claim.

The Official Action sets forth a rejection of original Claims 1-3 based on the disclosure contained in U.S. Patent No. 5,496,275 to *Sirhan et al.* in view of the disclosure contained in U.S. Patent No. 5,176,637 to *Sagae*. That rejection is respectfully traversed for at least the following reasons.

Independent Claim 1 is directed to a method for manufacturing a catheter. The catheter comprises an inner tube forming a first lumen and an outer tube arranged coaxially with the inner tube, with a second lumen being formed between the outer surface of the inner tube and the inner surface of the outer tube. As originally claimed, the method comprises inserting a mandrel for retaining the first lumen in the inner tube and applying an ultrasonic horn to the outer surface of the outer tube to produce ultrasonic waves to thereby fusion bond the inner surface of the outer tube to the outer surface of the inner tube.

The inventors here discovered that fusion bonding the inner surface of the outer tube to the outer surface of the inner tube through use of ultrasonic waves makes it possible to selectively heat generally only that region which is to be bonded, with the heat unlikely being transmitted to other regions. Because the outer tube and the inner tube are not significantly thermally deformed in regions apart from the bonded region, the second lumen is generally not blocked or narrowed. The method here can thus be implemented if desired without necessarily inserting a mandrel between the inner tube and the outer tube as is the case with other known methods. It is thus possible to bond the inner and outer tubes to one another in a shorter period of time compared to prior methods. Additionally, the appearance of the outer tube is not significantly impaired and fluid flow into and out of the inflatable member by way of the second lumen can be satisfactorily performed.

The Official Action correctly notes that *Sirhan et al.* does not disclose a method of fabricating a catheter that involves applying an ultrasonic horn to the outer surface of the outer tube to fusion bond an inner surface of an outer tube to an outer surface of an inner tube.

Sagae discloses a catheter having inner and outer tubes, with the distal end portion of the outer tube 2 being fixed to the inner tube 1 by way of a fixing member 5. The bottom of column 3 of *Sagae* states that the fixing member 5 can be welded to the outer and inner tubes 1,2 by heat, ultrasonic wave or adhesives. In the more detailed description beginning in line 23 of column 9, *Sagae* describes that the fixing member 5 is welded to the inner and outer tubes 1, 2 by positioning a heat shrinkable tube 74 on the outer tube 2 at a position where the outer tube 2 is to be fixed to the inner tube 1. The heat shrinkable tube 74 is then partially heated to

shrink part of the tube 74 and weld the fixing member 5 to the inner and outer tubes 1, 2. *Sagae* notes that one or more mandrels 72 are inserted into the outer tube 2 to prevent cuts 5a provided on the fixing member 5 from being filled up during the welding process.

Thus, the specific method described in *Sagae* for welding the fixing member to the inner and outer tubes 1, 2 involves the use of a heat shrinkable tube. While *Sagae* mentions that the fixing member can be welded to the inner and outer tubes 1, 2 by heat, ultrasonic wave or adhesives, nowhere does *Sagae* state that adhesives and ultrasonic welding are functionally equivalent and that the two can be used interchangeably in all applications. Further, to the extent it can be said that the reference in *Sagae* to welding by ultrasonic wave has some application to the disclosure in *Sirhan et al.*, it is significant to note that *Sagae* discloses this in the context of welding a fixing member to the inner and outer tubes of a catheter. Thus, if one were somehow motivated to apply the disclosure in *Sagae* to the catheter disclosed in *Sirhan et al.*, one would weld a fixing member between the outer and inner tubes in the catheter disclosed in *Sirhan et al.* in accordance with the method described in *Sagae*. The method at issue here differs from such a modified method in that the method at issue here involves applying ultrasonic waves to utilize heat generation at the contact surface between the inner surface of the outer tube and the outer surface of the inner tube to fusion bond the inner surface of the outer tube to the outer surface of the inner tube. This is to be contrasted with the disclosure in *Sagae* in which the outer surface of the inner tube is welded to the inner surface of the fixing member, and the outer surface of the fixing member is welded to the inner surface of the outer tube.

Independent Claim 1 has been amended to delete the recitation relating to the ultrasonic horn and to make clear that the application of ultrasonic waves produces heat generation at the contract surface between the inner surface of the outer tube and the outer surface of the inner tube to fusion bond the inner surface of the outer to the outer surface of the inner tube. The method disclosed in *Sagae* does not involve generating heat at the contract surface between the inner surface of the outer tube and the outer surface of the inner tube to fusion bond the inner surface of the outer to the outer surface of the inner tube. Accordingly, if one were somehow motivated modify the method disclosed in *Sirhan et al.* based on the disclosure contained in *Sagae*, the resulting method would not be that which is recited in independent Claim 1. It is thus respectfully submitted that the method defined in independent Claim 1, and the various dependent claims, is patentably distinguishable over a hypothetical combination of the disclosures contained in *Sirhan et al.* and *Sagae*.

New dependent Claim 10 recites that the ultrasonic waves are applied without any mandrel being positioned between the inner surface of the outer tube and the outer surface of the inner tube. As noted above, *Sagae* specifically describes that one or more mandrels 72 are necessary to prevent the cuts 5a in the fixing member 5 from being filled up. Thus, new dependent Claim 10 is further distinguishable over a hypothetical combination of the disclosures contained in *Sirhan et al.* and *Sagae*.

Early and favorable action with respect to this application is respectfully requested.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application, the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: June 14, 2004

By: Matthew L. Schneider
Matthew L. Schneider
Registration No. 32,814

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-66201